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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,033	08/17/2001	Patricia C. Allen	0217.01	2685

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/05/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,033

Applicant(s)

Allen et al

Examiner

Portner

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 2, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-11 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 1-11 are pending; claim 1 has been amended.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Withdrawn

2. Claims 1-11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, in light of the amendment of the claims to recite an "effective" amount.
3. Claims 1-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in view of Stimpel et al, in light of the arguments made of record by Applicant.

Allowable Subject Matter

4. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

New Grounds of Rejection

Claim Rejections - 35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Schraner et al (1989, abstract).

The claimed invention is directed to a composition that comprises an Echinacea preparation together with a carrier, wherein the carrier is a carrier that can be fed to poultry.

Schraner et al (1989) disclose a composition that comprises an Echinacea preparation (see abstract line 5) together with a carrier (solvent), wherein the carrier is a carrier that was fed to poultry (leghorn chickens).

The reference anticipates the instantly claimed compositions, as the recited intended use of the composition does not define over the disclosure of the prior art.

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7. Claims 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Hockertz, S (1990, abstract).

The claimed invention is directed to a composition that comprises an Echinacea preparation able to effect the immune response to coccidial antigen.

Hockertz disclose a composition that comprises an Echinacea preparation (see abstract line 5) , wherein the preparation was able to induce killing of protozoa, a type of coccidial pathogen.

The reference anticipates the instantly claimed compositions.

8. Claims 8-9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kutilek, III et al (US Pat. 5,770,217).

The claimed invention is directed to a dietary composition that comprises Echinacea, wherein the Echinacea is of an amount about 0.5% w/w and comprises an ingestible carrier for poultry.

Kutilek, III et al (US Pat. 5,770,217) claims a dietary composition that comprises Echinacea, wherein the Echinacea is of an amount about 0.5% w/w, and also comprises an ingestible carrier (excipient: see claim 1 and 11), and evidences anti-protozoal activity.

The composition is disclosed for the administration to poultry, turkeys, gallinaceous birds, ostriches and birds held in captivity in aviaries (see col. 3, lines 31-37). The reference inherently anticipates the instantly claimed invention.

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9. Claims 8 and 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Squires (US Pat. 6,355,684)

The claimed invention is directed to a dietary composition that comprises an Echinacea, wherein the Echinacea is Echinacea purpurea and comprises an ingestible carrier for bird, farm animals. *see clm 12*

Squires (US Pat. 6,355,684) claim a dietary composition that comprises Echinacea purpurea, together with a carrier, wherein the carrier may be a grain powder, corn meal, fatty acids or vegetable oil (see claim 4, as well as col. 15, lines 24-54).

The composition is disclosed to be effective against microbial pathogens (see col. 5, lines 46-48), to include bacteria, viruses and fungi, wherein the composition is for the administration to birds (see claim 12, col. 24, line 31 and 32). The composition is also disclosed to comprise an active substance against protozoa (see col. 7, lines 10-11). The reference inherently anticipates the instantly claimed invention.

Claim Rejections - 35 U.S.C. § 103

10. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kutilek, III et al (US Pat. 5,770,217) in view of Schraner et al (1989) and Davis et al (US Pat. 4,544,548).

The claimed invention is directed to a method of protecting poultry against coccidiosis, the method comprising the steps of inoculating chicks with an anticoccidial vaccine and providing

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a dietary regimen composition comprising Echinacea for enhancing an immune responses to said vaccine and an ingestible carrier.

See discussion of Kutilek, III et al above. The Echinacea dietary supplement is taught to have anti-protozoal (anti-coccidial) activity (see col. 5, lines 14), to function as a broad spectrum antibiotic (see col 5, lines 1-16), and to induce an immune response.

Kutilek, III et al teach a method, the method comprising the steps of :

self inoculating a subject (poultry, turkeys, gallinaceous birds, ostriches, birds held in captivity in aviaries (see '217, col. 3, lines 31-37)) with an Echinacea dietary supplement of about 0.5% by weight (see '217, claim 1 and claim 18); and

providing an additional anti-coccidial component and ingestible carrier, wherein Kutilek, III et al teach the combination of the anti-coccidial Echinacea composition in association with an additional anti-coccidial component but differs from the instantly claimed invention by failing the additional anti-coccidial component to be a coccidial vaccine.

Schranner et al (1989, abstract) show Echinacea together with an antigen formulated for administration to poultry in an analogous art for the purpose of stimulating an enhanced immune response in the chicken.

Davis et al teach and show poultry dietary compositions that comprise an anti-coccidial vaccine (see Davis claim 1 and col. 10, lines 9-10) with an ingestible poultry feed carrier (see '548: col. 4, line 14; col. 8, line 13; col. 10, line 10-11) together with an additional anti-coccidial

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agent in an analogous art for the purpose of obtaining a protective/appropriate immune response (see col. 6, lines 31-35) through the simultaneous (see col. 6, lines 13-17) or sequential (separately, see col. 6, lines 43-45) inoculation of poultry or day old chicks (see claim 3 of '548, new born chicks).

It is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows ^{logically} ~~totally~~ from their having been individually taught in the prior art. In re Kerkhoven (205 USPQ 1069, CCPA 1980).

The person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining an enhanced protective immune response in chickens upon inoculation with a formulated ~~an~~ anti-coccidial dietary composition that comprises an anticoccidial vaccine together with anti-coccidial immune response enhancing component in an ingestible carrier, wherein anti-coccidial immune response enhancing component is Echinacea because Kutilek, III et al, Schraner et al (1989) and Davis et al (US Pat. 4,544,548) all teach composition for inoculating poultry; Kutilek, III et al and Davis et al (US Pat. 4,544,548) inoculate with dietary regimen compositions that comprise anti-coccidial components, wherein Kutilek, III et al (US Pat. 5,770,217) inoculates with Echinacea and Davis et al inoculates with an anti-coccidial vaccine and in view of the fact that Echinacea has been shown to enhance an induced immune response to a heterologous antigen in a chicken by Schraner et al, the combined

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composition would induce a protective immune response in poultry which was enhanced due to the presence of an effective amount of Acinic.

In the absence of a showing of unexpected results, the references obviate the instantly claimed invention.

11. Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kutilek, III et al (US Pat.'217) in view of Davis et al ('548) and Schraner et al (1989) and further in view of Squires (US Pat. 6,355,684).

The claimed invention is directed to a method of protecting poultry against coccidiosis, the method comprising the steps of inoculating chicks with an anticoccidial vaccine and providing a dietary regimen composition comprising Echinacea for enhancing an immune responses to said vaccine and an ingestible carrier, wherein the Echinacea is Echinacea purpurea.

See discussion of Kutilek, III et al in view of Davis et al and Schraner et al (1989) above. The combined references teach a method of protecting poultry against coccidiosis, the method comprising the steps of inoculating chicks with an anticoccidial vaccine and providing a dietary regimen composition comprising Echinacea for enhancing an immune responses to said vaccine and an ingestible carrier but differ from the instantly claimed invention by failing to show the Echinacea to be Echinacea purpurea.

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Squires (US Pat. 6,355,684) teach Echinacea purpurea dietary supplements in an analogous art for the purpose of inoculating a bird, or farm animal (see, col. 24, claim 12; claim 11) to protect against disease.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the Echinacea composition of Kutilek, III et al with the Echinacea purpurea composition of Squires because Squires et al teaches dietary compositions for birds and farm animal that comprise Echinacea purpurea is safe for administration to animals (see col. 5, line 15) which provides surprising good and consistent results (see col. 4, lines 65-67) and is combinable with other bioactive components active against protozoa (see col. 7, lines 9-10).

It is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows ^{logically} ~~locally~~ from their having been individually taught in the prior art. In re Kerkhoven (205 USPQ 1069, CCPA 1980).

Conclusion

12. This is a non-final action.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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14. Thaxton (US Pat. 5,311,841) is cited to show a method of inoculating day old chicks with combination vaccines and medicaments to induce a protective immune response against coccidiosis. (See col. 3, lines 40-68; col. 4, lines 1-2; claims).

15. Vukovic, Laurel "The best herbs for every stage of your life. (Consumer guide), September 1998, teaches Echinacea to strengthen the immune system to attack protozoa and to strengthen cells against invading microorganisms.

16. Rehman, J et al (1999) teach Echinacea is able to potentiate the production of antigen-specific immunoglobulin (abstract).

17.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp August 29, 2002


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